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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,835	10/22/2001	Mark B. Rabin	044921-5047-02	8480
9629	7590	10/02/2003	EXAMINER	
MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			WILDER, CYNTHIA B	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/982,835	RABIN, MARK B.	
	Examiner	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 67-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 67-84 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's preliminary amendment filed in February 20 2002 is acknowledged. Claims 1-66 have been canceled. Claims 67-84 are pending. The following election/restriction requirement is regards to the different mutations recited in the claims 67-84.
2. The claims 67-84 contain claims with regard to specific Polymorphisms (i.e. mutations) selected from any of Tables 3, 4, 5, 6 or 7. Election of *one* polymorphism is required from one of the Tables 3, 4, 5, 6 or 7. The broad claims 67-84 will be examined along with the *single* (mutation) which is elected.
3. Each of the polymorphisms is unrelated to each other polymorphism. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806. 04, MPEP 808.01). In the instant case the different inventions are unrelated because each mutation differs in structure and effect from each other mutation. Specifically, the chemical structure of any mutation is necessarily different from that of any other mutations because where, for example, in Table 3, a non-sense mutation as recited is chemically and structurally different single nucleotide deletion as recited in Table 4 or the single nucleotide insertion mutation as recited in Table 6. With regard to the different effect, the specification teaches that some of the mutations listed causes truncation associated with cancer while other mutations listed results in a non-functional protein. These changes cause different effects in different genes, as well as clearly resulting in different structures.

Two requirements are cited in 37 C.F.R. 1.142 to permit restriction. "If two or more independent and distinct inventions are claimed in a single application, the examiner in his/her action shall require the Applicant in his/her response to that action elect that invention to which his/her claim shall be restricted, this official action being called a requirement for restriction (also known as a requirement for division). If the distinctness and independence of the invention be clear, such requirement will be made before any action on the merits; however, it may be made at any time before final action in the case, and the discretion of the examiner."

These two requirements are that the invention be independent and distinct. MPEP 801 notes regarding the independent requirement that "The term "independent" (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect". Here, the mutations are unconnected to each other in design, since they differ in structure, The mutations are different in operation, since they act at different sites and cause different effects, as noted above. With regard to the distinct requirement, the MPEP 801 notes "The term "distinct" means that two or more subjects as disclosed are related, for example, as combination and part (subcombination) thereof, process and apparatus for its practice, process and product made, et c., but are capable separate manufacture, use or sale as claimed, a AND ARE PATENTABLE (novel and unobvious) OVER EACH OTHER (though they may each be unpatentable because of the prior art)." Thus, the specific requirement is that the inventions are capable of separate use, which is clearly evident in this application regarding these mutations both by the separate claiming and because each mutation can be separately screened against the BRCA1 genome. Further, each mutation is separately patentable over each other mutations

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4. Because these invention are distinct for the reasons given above and the search required for any one mutation is not required for any other mutation, restriction for examination purposes as indicated is proper.

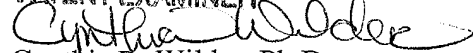
5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 9:30 am to 6:30 pm and on Friday from 9:30 am to 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308 0196.

CYNTHIA WILDER
PATENT EXAMINER



Cynthia B. Wilder, Ph.D.

Examiner

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September 27, 2003